



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Confidentiality of Substance Use Disorder Patient Records

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of Public Meeting

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) announces that it will hold a public listening session on Wednesday, January 31, 2018, to solicit information concerning the Confidentiality of Substance Use Disorder Patient Records regulations as required by Section 11002 of the 21st Century Cures Act. The listening session will provide an opportunity for the public to provide input to SAMHSA concerning the effect of part 2 on “patient care, health outcomes, and patient privacy” as well as potential regulatory changes and future subregulatory guidance.

DATES: The listening session will be held on Wednesday, January 31, 2018, from 8:30 AM (Eastern) to 1:00 PM (Eastern)

FOR FURTHER INFORMATION CONTACT: For information concerning the listening session, please contact Rachel Karton, Senior Legislative and Regulatory Analyst, SAMHSA, 5600 Fishers Lane, Rockville, MD 20857, (240) 276-0416 or email PrivacyRegulations@SAMHSA.hhs.gov.

SUPPLEMENTARY INFORMATION:

Participation: The Listening Session proceeding will be recorded, and subsequently archived and posted on the SAMHSA website. The public may attend the listening session:

- Via Teleconference/Webcast: The entire proceeding will be streamed live over the Internet (requires prior registration). Audio and streaming information will be sent to those who

register prior to the meeting. Capacity for the Teleconference/Webcast participation is limited so early registration is recommended.

- **In Person:** The address for this meeting is 5600 Fishers Lane, 5th (Main) Floor Pavilion rooms, Rockville, Maryland 20852. The building is a federal facility; prior registration, a security screening and a federally-approved identification (e.g., driver's license) are required to attend in-person. Capacity for in-person attendance is limited so early registration is recommended.

Registration: Registration is required for participation in the listening session in person or via Teleconference/Webcast. Registration is now open. Registration for the in-person session will close on 01/22/2018 at 12:00 p.m. Eastern Time (ET). Registration for the Teleconference/Webcast will close on 01/31/2018 at 8:30 a.m. ET. Persons registering should indicate if they wish to make a public comment. SAMHSA recommends that when commenters suggest changes or revisions to current regulations that they indicate specifically, when feasible, how such regulation text should be revised. Only one representative of an organization may be allowed to present oral comments. Presentations will be limited to three minutes per speaker. SAMHSA will try to accommodate all speakers who wish to present based on the time allotted for this meeting. Persons making oral presentations are encouraged to also submit written comments as discussed below.

To register, go to: <https://42-cfr-part2-listening-session.eventbrite.com>

Special Assistance: Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Rachel Karton (contact information provided below) at least 10 days prior to the meeting.

Public Comments: In addition to attending the session in person or joining via Teleconference/Webcast, the Agency offers several ways to provide comments. SAMHSA recommends that when commenters suggest changes or revisions to current regulations that they indicate specifically, when feasible, how such regulation text should be revised. You may provide comments through the following means:

- Electronically: *PrivacyRegulations@SAMHSA.hhs.gov* (preferred).
- Regular, Express or Overnight Mail, or Hand Delivery or Courier: Written comments must be sent to the following address ONLY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services, Attn: Mitchell Berger, SAMHSA, 5600 Fishers Lane, Room 18E89C, Rockville, Maryland 20852. Due to the anticipated high volume of comments, please note that receipt of comments will not be acknowledged. Comments must be received by 5:00 p.m. ET on Wednesday February 28, 2018.

BACKGROUND: Title 42, section 290dd-2, of the United States Code, pertaining to Confidentiality of Records, provides that “[r]ecords of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall [...] be confidential and be disclosed only for the purposes and under the circumstances expressly authorized” by the statute or as otherwise provided. The statute further provides that such records may not be “used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient” without an appropriate court order.

The implementing regulations, 42 CFR part 2, were first promulgated as a final rule on July 1, 1975 (40 FR 27802), and substantively updated in 1987 (52 FR 21796). On February 9, 2016, SAMHSA issued a notice of proposed rulemaking (NPRM) regarding substantive changes to part 2 (81 FR 6987) and on January 18, 2017, SAMHSA finalized changes to these regulations (82 FR 6052). The January 2017 final rule became effective on March 21, 2017 (see 82 FR 10863, Feb. 16, 2017). This final rule was intended to “ensure that patients with substance use disorders have the ability to participate in and benefit from health system delivery improvements, including from new integrated health care models while providing appropriate privacy safeguards.” The final rule made substantive changes to regulatory provisions regarding Definitions (§ 2.11), Applicability (§ 2.12), Confidentiality restrictions and safeguards (§ 2.13), Security for records (§ 2.16), Disposition of records by discontinued programs (§ 2.19), Consent requirements (§ 2.31), Re-disclosure (§ 2.32), Medical emergencies (§ 2.51), Research (§ 2.52), and Audit and evaluation (§ 2.53).

Concurrently with finalizing these changes, SAMHSA issued a supplemental notice of proposed rulemaking (SNPRM) on January 18, 2017, proposing additional changes to facilitate disclosures by lawful holders to their contractors, subcontractors, and legal representative for the purposes of payment and health care operations and for carrying out an audit or evaluation and to permit disclosures by lawful holders to those conducting audits and evaluations on behalf of a governmental agency providing financial assistance to or regulatory oversight over the lawful holder. SAMHSA also sought comments on other topics, including an option for an abbreviated prohibition on re-disclosure notice. In January 2018, SAMHSA published a final rule implementing these changes.

In response to the 2016 NPRM and since publication of the January 2017 final rule and the SNPRM, SAMHSA has already heard from numerous stakeholders on a range of issues pertaining to part 2. For instance, some commenters asserted that part 2 has become a barrier to integration of care and research. Many commenters also have suggested that part 2 does not adequately align with the Health Insurance Portability and Accountability Act (HIPAA).

SAMHSA also has received many comments emphasizing the continuing importance of part 2 in protecting patients who seek substance use disorder treatment from discrimination in housing, employment, education, and other settings as well as from criminal investigation and penalties. Some commenters also have urged SAMHSA to update part 2 penalty provisions and prevent what they believe to be misuse of patient identifying information.

On December 13, 2016, the 21st Century Cures Act was signed into law (P.L. 114-255). Section 11002 of this law requires that, within one year of the effective date of the final rule, “the Secretary [HHS] shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.” The listening session on January 31, 2018, will solicit input focused on how part 2 impacts patient care, health outcomes and patient privacy as well as potential regulatory changes and future subregulatory guidance. It is important to note that any recommendations of further changes to part 2 received during this meeting could, even if legally permissible and feasible, only be implemented after notice-and-comment as required by the Administrative Procedures Act.

Dated: January 3, 2017

Charles LoDico

Chemist

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